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52

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/718,580 | 11/24/2003 | Ludger Dinkelborg | SCH-1718 D01 | 1691 |
| 23599 | 7590 | 12/28/2004 | EXAMINER | |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | LACYK, JOHN P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,580

Applicant(s)DINKELBORG ET AL. **Examiner**

John P Lacyk

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13 and 28-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 10-13 and 28-30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Art Unit: 3736

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10-13, 28-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 now contains language directed to the adhesive being "solely" a peptide, a fat or gold, however the specification lacks proper support for such language. The specification, pages 5-6, describe the use of peptides, fats or gold but fail to specify that the only adhesive is a peptide, fat or gold. Lines 15-17 even state that the device includes an adhesive on the surface of the stent and an adhesive radioactive isotope, which would appear that the device uses two adhesives and not "only" or "solely" a peptide, fat or gold. Further it appears that the use of gold is also not "solely" gold since the gold is in combination with a thiol-group containing complexing agent. Further in view of the Suthanthiran et al reference which, as pointed out by applicant, states that it is "necessary" to combine the adhesive with an appropriate binder material it is unclear how the disclosed device would properly adhere "solely" using a peptide, fat or gold.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3736

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-13 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al in view of Suthanthiran et al.

Fischell et al disclose a stent having a radioactive isotope fixed on the surface of the stent. Fischell et al teaches that the radioactive isotope can be plated onto the surface which would inherently have some adhesive properties in order for the isotope to remain attached to the stent. However while Fischell et al does not specifically state the use of an adhesive, or that the adhesive is a peptide, fat or gold. Suthanthiran et al teaches a radioactive device used in the body and specifically teaches that it is known to fix an adhesive layer onto a carrier by use of an adhesive of polyamino acid (column 5, lines 39-45). Therefore a modification of Fischell et al such that the radioactive isotope is attached to the surface of a stent in any well know manner using any well known adhesive would have been obvious to one skilled in the art. Fischell et al also teaches that it is known to use different radioactive isotopes (alpha, beta, gamma) depending on the desired use and does teach Gold (Au) as one that is known to be used. While Suthanthiran et al does not teach "solely" using a peptide as an adhesive at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to only use a peptide as the adhesive because Applicant has not disclosed that using "solely" a peptide, fat or gold provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art,

Art Unit: 3736

furthermore, would have expected the above combination and applicant's invention, to perform equally well with either the peptide, fat or gold being the sole adhesive or used with a binder material because both adhesives would perform the same function of adhering the radioactive isotope to the stent equally well. Therefore, it would have been prima facie obvious to modify Fischell et al and Suthanthiran et al to obtain the invention as specified in claim 10 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

5. Applicant's arguments filed 10/07/2004 have been fully considered but they are not persuasive. As discussed above, the amendment lacks proper support in the specification for added limitations and the claims would still fail to patentably distinguish over the prior art.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

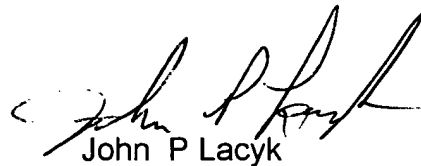
Art Unit: 3736

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 571-272-4728.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk